

**REMARKS**

Prior to entry of this amendment, claims 1-21 are pending in the instant application. Claims 1 and 12 are independent.

By this amendment, applicants amend claim 12.

Applicants appreciate the Examiner's acknowledgement of applicants' claim for foreign priority and receipt of a certified copy of the priority document.

Applicants appreciate the Examiner's acceptance of the original drawings filed on March 18, 2004.

Applicants appreciate the Examiner's consideration of applicants' Information Disclosure Statements filed March 18, 2004, September 22, 2004, and March 23, 2006.

Claims 1-21 are presented to the Examiner for further consideration on the merits.

**A. Introduction**

In the outstanding, non-final Office action, the Examiner rejected claims 1-10 and 12-21 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter; rejected claims 1, 11-14 and 21 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,183,042 to Harjunmaa et al. ("the Harjunmaa et al. reference"); and indicated the presence of allowable subject matter.

**B. Rejection of Claims 1-10 and 12-21 as Being Directed to Non-Statutory Subject Matter**

In the outstanding, non-final Office action, the Examiner rejected claims 1-10 and 12-21 under 35 U.S.C. § 101, because the claimed invention is directed to non-statutory subject matter.

Applicants thank the Examiner for providing suggestions on amending independent claim 12. Applicants amended independent claim 12 to include the phrase "adapted to be," as suggested by the Examiner. Accordingly, applicants respectfully request that the rejection of

claim 12 under 35 U.S.C. § 101 be withdrawn. Since claims 13-21 depend on claim 12, these claims also satisfy the requirements of 35 U.S.C. § 101. Therefore, applicants respectfully request that the rejection of claims 13-21 also be withdrawn. However, applicants respectfully traverse the rejection of claims 1-10, for at least the following reasons.

The grounds of rejection set forth that method claim 1 does not result in a “physical transformation nor does it appear to provide a useful and tangible result.” The grounds of rejection set forth that there is no “tangible result because estimating a concentration of a blood component is nothing more than a computation within a processor.” Further, the grounds of rejection advance that the method of claim 1 “fails to use or make available for use the result of the blood component concentration determination to enable its functionality and usefulness to be realized.” Applicants respectfully disagree.

Claim 1 satisfies the statutory requirements under 35 U.S.C. § 101 because it provides a useful, concrete, and tangible result. The U.S. Court of Appeals for the Federal Circuit in Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1055, 22 U.S.P.Q.2d (BNA) 1033 (Fed. Cir. 1992) analyzed a method claim under 35 U.S.C. § 101. Method claim 1 recited the following:

A method for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high frequency energy in the late QRS signal, comprising the steps of:

converting a series of QRS signals to time segments, each segment having a digital value equivalent to the analog value of said signals at said time;

applying a portion of said time segments in reverse time order to high pass filter means;

determining an arithmetic value of the amplitude of the output of said filter; and

comparing said value with said predetermined level. Id.

The court held that “[t]hese steps of ‘converting’, ‘applying’, ‘determining’, and ‘comparing’ are physical process steps that transform one physical, electrical signal into another.” Id. at 1059. The court stated that “[t]he view that ‘there is nothing necessarily physical about ‘signals’ is incorrect.” Id. citing In re Taner, 681 F.2d 787, 790, 214 U.S.P.Q. 678, 681 (CCPA 1982). The court held that method claim 1 contained statutory subject matter. Id. at 1060.

Applicants consider this case relevant to the rejection of claim 1 of the instant application. The method of claim 1 in Arrhythmia Research Tech., Inc. v. Corazonix Corp., did not recite that the steps of determining and comparing the values be stored or displayed, as suggested by the Examiner, in order to satisfy the requirements of 35 U.S.C. § 101. In this regard, applicants respectfully submit that the Examiner is attempting to unnecessarily limit method claim 1 of the instant application. That is, the grounds of rejection advance an interpretation of the requirements of 35 U.S.C. § 101 that is contrary to the U.S. Court of Appeals for the Federal Circuit.

Additionally, the grounds of rejection set forth that the practical application needs to be “explicitly recited” in the claims. Applicants respectfully disagree that the practical application of method claim 1 needs to be “explicitly recited” in claim 1 in order to satisfy the requirements of 35 U.S.C. § 101. The estimation of the concentration of the blood component is not an abstract number or figure, but relates to the subject, a human being. As in Arrhythmia Research Tech., Inc. v. Corazonix Corp., the practical applications of measuring a concentration of a blood component are *understood by anyone* reading method claim 1 of the instant application, without explicitly reciting these applications (*emphasis added*). For example, it is understood that

knowing the concentration of blood of a human being would relate to a person's state of health, or more generally to applications in the medical field.

For at least these reasons, applicants respectfully submit that claims 1-10 satisfy the requirements of 35 U.S.C. § 101. Accordingly, applicants respectfully request that the rejection of claims 1-10 under 35 U.S.C. § 101 be withdrawn.

C. Asserted Anticipation Rejection of Claims 1, 11-14 and 21

In the outstanding, non-final Office action, the Examiner rejected claims 1, 11-14 and 21 under 35 U.S.C. § 102(b) as being anticipated by the Harjunmaa et al. reference. Applicants respectfully traverse this rejection, for at least the following reasons.

Claim 1 recites, *inter alia*, establishing a statistical model using the first differential absorption spectrum and the actually measured concentrations, and estimating the concentration of the blood component using a second differential spectrum based on the statistical model. The grounds of rejection set forth that col. 4, lines 22-36 and 52-63, col. 5, lines 6-15 and col. 6, lines 26-34 of the Harjunmaa reference disclose these steps of claim 1. Applicants respectfully disagree.

There is nothing in the Harjunmaa et al. reference that corresponds to “establishing a statistical model using the first differential absorption spectrum and the actually measured concentrations,” as recited in claim 1. Rather, the Harjunmaa reference describes five (5) values or signals used for calculation: (1) *a difference signal* obtained when the master lamp 10 is on and the slave lamp 12 is off (col. 4, lines 22-36); (2) *a residual signal* when both the master lamp 10 and the slave lamp 12 are on (col. 4, lines 37-51); (3) *a digital signal* obtained after the adjustable gap mechanism 26 releases pressure on, for example, the fingerweb, increasing the thickness of tissue (col. 4, lines 52-65); (4) *a proportionality constant* (col. 5, lines 10-11); and

(5) a *correction term* obtained from a personal calibration step (col. 5, lines 12-15 and col. 6, lines 25-34).

Col. 5, lines 6-15 of the Harjunmaa et al. reference describe how a calculation of glucose content is performed using the above signals or values. The *residual signal* is subtracted from the *digital signal* which is divided by the *difference signal*  $((3-2)/1)$ . Next, the *proportionality constant* is applied to the resultant term. Also, if necessary, the *correction term* is also factored in.

Given the above, there is nothing remotely suggestive of establishing a statistical model. The calculation of the glucose content of the Harjunmaa et al. reference, as performed by the processor 22, which includes subtracting the *residual signal* from the *digital signal*, and dividing by the *difference signal*  $((3-2)/1)$ , does not correspond to “establishing a statistical model.” Rather, as described in the Harjunmaa et al. reference, it is simply an equation to calculate the glucose content, and not a statistical model.

Even assuming, *arguendo*, that the  $((3-2)/1)$  corresponds to a statistical model, method claim 1 recites “estimating the concentration of the blood component using a second differential absorption spectrum obtained with respect to the body part based on the statistical model.” However, the Harjunmaa et al. reference describes simply applying a previously determined *proportionality constant* to the resultant of  $((3-2)/1)$  in order to determine the glucose content, which does not even suggest the claimed estimating of method claim 1.

For at least these reasons, the Harjunmaa et al. reference fails to disclose or suggest all the steps of method claim 1. Accordingly, applicants respectfully request the rejection of claim 1 be withdrawn. Since claim 11 is patentable at least by virtue of its dependency on claim 1, applicants respectfully request the rejection of claim 11 also be withdrawn.

Claim 12 recites, *inter alia*, a spectroscope that separates the light emitted from the light source into components of different wavelengths. The grounds of rejection set forth that the beam combiner 17 of the Harjunmaa et al. reference corresponds to and discloses this element of the apparatus of claim 1. Applicants respectfully disagree.

The Harjunmaa et al. reference describes that lenses 15 and 16, respectively, direct “the beams to a beam combiner 17, where the two substantially monochromatic beams are optically combined or time multiplexed together into a single beam” (col. 3, lines 55-57)(*see also*, col. 6, lines 42-47, describing *multiplexing* more than two wavelengths into one measuring beam). On its face, the beam combiner 17 does not correspond to the claimed spectroscope, since the beam combiner 17 does not “separate” the light, nor does the beam combiner 17 separate the light “into components of different wavelengths.”

Applicants respectfully submit that the grounds of rejection set forth an interpretation that is an utter departure from the plain meaning of a spectroscope. That is, such an interpretation is not consistent with how one of ordinary skill in the art would interpret a spectroscope, and conflicts with the meaning given to a spectroscope in other patents from analogous art (MPEP §2111.01 - Plain Meaning).

Additionally, for reasons analogous to those discussed above in regards to claim 1, the processor 22 of the Harjunmaa et al. reference fails to correspond to or disclose the signal processor of claim 12. The Harjunmaa et al. reference fails to disclose establishing a statistical model or estimating a second differential absorption spectrum based on the statistical model, as recited in the signal processor recitation of claim 12.

For at least these reasons, the Harjunmaa et al. reference fails to disclose or suggest all the elements of claim 12. Accordingly, applicants respectfully request that the rejection of claim

12 be withdrawn. Since claims 13, 14, and 21 are patentable at least by virtue of their dependency on claim 12, applicants respectfully request the rejection of claims 13, 14, and 21, also be withdrawn.

D. Allowable Subject Matter

Applicants appreciate the Examiner's indication of allowable subject matter in the claims, apparently recited in claims 2-10 and 15-20. However, applicants respectfully submit that *all* of the pending claims are patentable over the cited prior art.

E. Conclusion

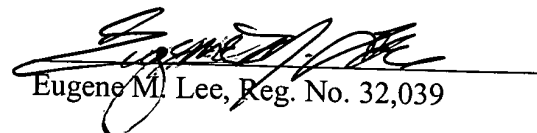
If the Examiner believes that additional discussions or information might advance the prosecution of the instant application, the Examiner is invited to contact the undersigned at the telephone number listed below to expedite resolution of any outstanding issues.

In view of the foregoing amendments and remarks, reconsideration of this application is earnestly solicited, and an early and favorable further action upon all the claims is hereby requested.

Respectfully submitted,

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PETITION and  
DEPOSIT ACCOUNT CHARGE AUTHORIZATION

This document and any concurrently filed papers are believed to be timely. Should any extension of the term be required, applicant hereby petitions the Director for such extension and requests that any applicable petition fee be charged to Deposit Account No. 50-1645.

If fee payment is enclosed, this amount is believed to be correct. However, the Director is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1645.

Any additional fee(s) necessary to effect the proper and timely filing of the accompanying-papers may also be charged to Deposit Account No. 50-1645.